

Fig 1

Study Setup

- Clinical Study Definition
 - Describes Sponsors & Investigators
 - Declares Subject Attributes to Capture
 - Associates Specific Lab Procedures with a Clinical Study
 - Defines Genotype Results to Report

Study Protocol

Study Number: 632-001

Sponsor Study Number: 198-005

Sponsor Company: A CO., JOHN DOE, Ph.D.

Sample test: SS1

PS1

DAVID JONES

JOHN DOE, Ph.D.

Sponsor Study No.: 198-005

Study No.: 632-001

Investigator: JOHN DOE, Ph.D.

Final Storage Tube Range: 1-4

Cascade Accession Number

Barcode Length: 10

New

Modify

Delete

Save

Cancel

Done

Sponsor Protocol Title: Pharmacokinetic Evaluation of Dose(R) (oxbutylin chloride) and IR oxbutylin Administered Alone and in the Presence of Ketoconazole

PPGx Protocol Title: Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "G", and "H" alleles

Procedures: DNA Isolation, 3 mL whole blood, Purgene K21 SpectroMax DNA quantitation CYP2C9-3 CYP2C9-2 Ver. 7

Subject Attributes: Subject Number Gender Birthdate Ethnicity

Created: DNALIMS 10/4/99 12:02

Modified: DNALIMS 10/5/99 14:38

FIG. 2

Accessioning

Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Worklist Workflow

Accessioning

Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS22156	09-OCT-1999	
632-001	A100124	BA10113	PS22157	09-OCT-1999	
632-001	A100125	BA10114	PS22158	09-OCT-1999	
632-001	A100126	BA10115	PS22159	09-OCT-1999	

PPGx Study No: [532001] Sponsor: [A Co. (JOHN DOE, Ph.D.)] Print Save As a Worklist Query

Accession No: [A100126] Date Received: [09-Oct-1999] Sample Type: [Fresh Whole Blood]

Sponsor Sample Tube ID: [BA10115] Tube 1 Tube 2 Tube 3 Tube 4

PPGx Sample Tube ID: [PS22159]

Sample Tube Volume: [5] [5] [5] [5]

Sample Condition: [Good] [Good] [Good] [Good]

Comments: [Subject Attributes: Subject Number: 15678, Gender: M, Birthdate: 19-Sep-88, Ethnicity: Black]

Add Comments: []

Created: [10/9/99 20:03] Modified: []

DNALIMS: []

Buttons: New, Save, Delete, Cancel, Modify, Close

FIG. 3

Sample Tracking

- Supports Multiple Container Classes
- Allows User Defined Container Geometries & Templates
- Maintains Sample & Container Location
- Permits Flexible Sample Loading & Rearrangement
- Tracks and Maintains Container & Sample Ownership

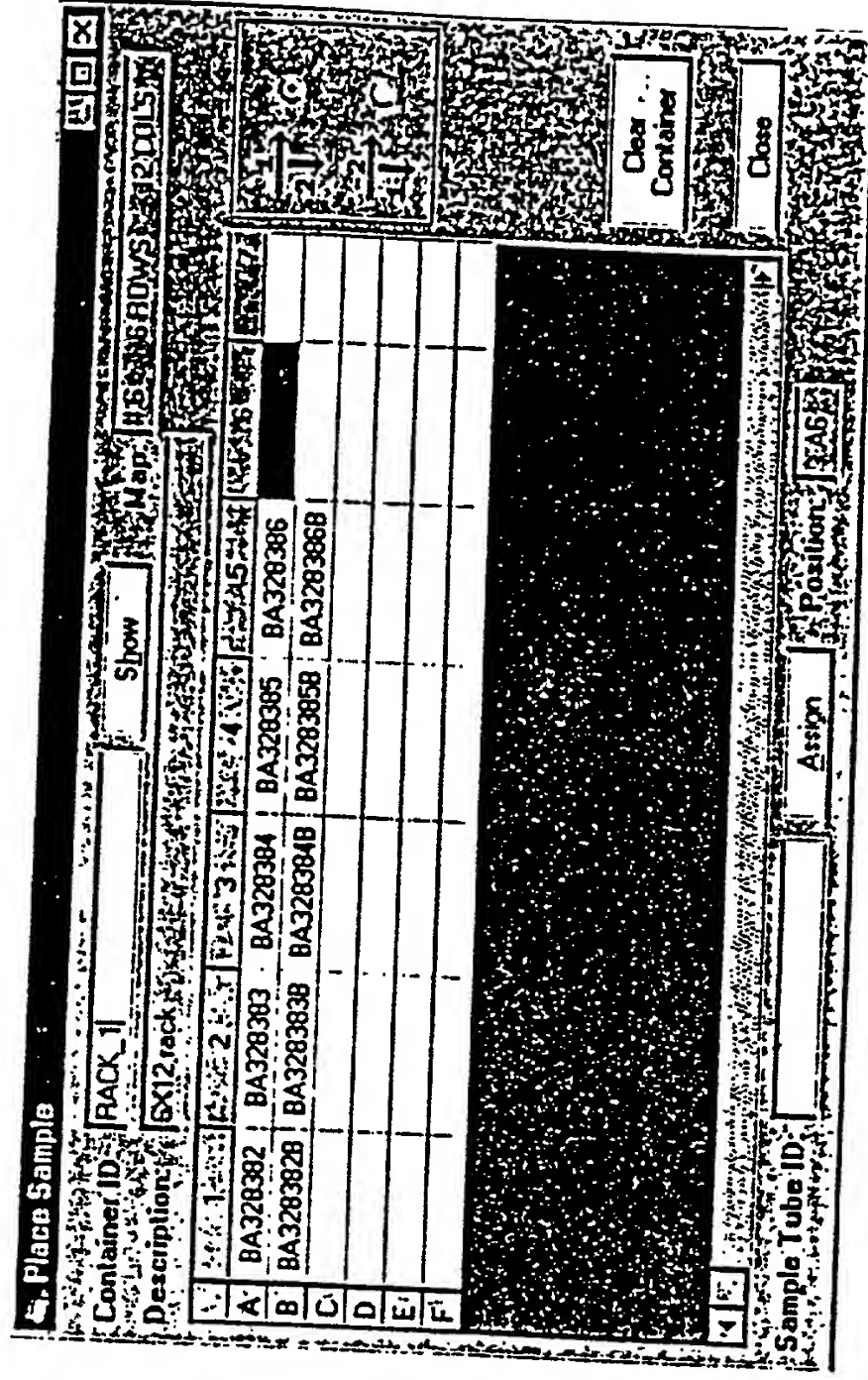


FIG. 4

Electronic Procedure Checklists

- Automates Laboratory Process Tracking
- Supports Standard Operating Procedures
- Maintains Uniform Laboratory Processes
- Records Chain of Custody
- Tracks Repeat Operations

Procedure	Created By	Created On	Locked For	Query
DNA Isolation, 3 mL whole blood, Purgene K1	DNALIMS	10/5/99 13:57	DNALIMS	
CYP2C9 Ver. 6	DNALIMS	10/5/99 14:19		
CYP2C9 Ver. 7	DNALIMS	10/5/99 14:39		
CYP2C9 Ver. 8	DNALIMS	10/5/99 14:40		
CYP2C9 Ver. 9	DNALIMS	10/5/99 14:52	DNALIMS	

Procedure	Notes	ALL SAMPLES	Created On	Locked For	Query
Thaw frozen blood		<input type="checkbox"/>	BA100100	BA100101	BA
Gently mix sample		<input type="checkbox"/>			
Transfer 3 mL of blood to Lysis tube		<input type="checkbox"/>			
Add 9 mL of RBC lysis to RBC lysis tube		<input type="checkbox"/>	DONE	CA1111	CA1112
Mix and incubate 10 minutes at room temperature		<input type="checkbox"/>	DONE	CA1111	CA1112
Centrifuge 10 minutes at 3000RPM		<input type="checkbox"/>			
Pour off supernatant into biohazardous waste		<input type="checkbox"/>	11009	11009	
Resuspend cell pellet by vortexing		<input type="checkbox"/>			
Add 3 mL of RBC lysis to RBC lysis tube		<input type="checkbox"/>	DONE	CA1111	CA1112

Procedure	Created By	Created On	Locked For	Query
DNA Isolation, 3 mL whole blood, Purgene K1	DNALIMS	10/5/99 13:57	DNALIMS	
CYP2C9 Ver. 6	DNALIMS	10/5/99 14:19		
CYP2C9 Ver. 7	DNALIMS	10/5/99 14:39		
CYP2C9 Ver. 8	DNALIMS	10/5/99 14:40		
CYP2C9 Ver. 9	DNALIMS	10/5/99 14:52	DNALIMS	

FIG. 6

Procedure:	Status:	SOP Number:	SOP Version:
DNA Isolation, 3 mL whole blood, Purgene Kit	APPROVED	GEN9709	C
2D6 Allele (A) Identification	APPROVED	CYP2D6A	A
SpectroMax DNA quantitation	APPROVED	MAX9802	A
CYP2C9-3	APPROVED	CYP2C9-3	A
CYP2C9-2 Ver 7	APPROVED	CYP2C9-2	A
CYP2C9-2 Ver 6	APPROVED	CYP2C9-2	A
Procedure Name:	Print		
2D6 Allele (A) Identification	Save As...		
Procedure Description:			
Laboratory Protocol for Identification of CYP2D6 'A' Allele by RFLP-PCR			
Gene:	SOP Number:	CYP2D6A	
Allele:	SOP Version:	A	
Status:		APPROVED	
New		Cancel	
Modify		Close	
Delete			
Created:	Modified:		
DNALIMS	DNALIMS	10/4/99:12:02	10/5/99:10:59

7
G
F

Multiple Types:

- Transfer
 - Dilution
 - Concentration Adjustment
 - Sample Preparation
- Highly Customizable
Plug-in Architecture to
Add New Types
Interfaces to Automation



86E

Auditing

Track Changes in Database

- Study
- Lab Procedures
- Sample
- Results

Flexible Audit Reporting Chain of Custody by Accession

Audit Report						
Protocol Audit Trail	AUDIT_ID	PROTOCOL_ID	SPONSOR_STU	TITLE_PPGX_STUDY_PPGX_PROTOCOL_TITLE	CREATED BY	DATE
STUDY_PROTOCOL						
	885	01	AIA	Evaluation of STUDY-1	x	DNALIMS
	890	01	AIA	Evaluation of STUDY-1	x	DNALIMS
	901	01	AIA	Evaluation of STUDY-1	x	DNALIMS
	951	01	AIA	Evaluation of STUDY-1	x	DNALIMS
	953	01	AIA	Genomic DNA Isolation and DNALIMS		DNALIMS
	957	01	AIA	Genomic DNA Isolation and DNALIMS		DNALIMS
	980	01	PHO-001	Genomic DNA Isolation and DNALIMS		DNALIMS
	984	01	PHO-001	Genomic DNA Isolation and DNALIMS		DNALIMS
	974	01	PHO-001	Genomic DNA Isolation and DNALIMS		DNALIMS
	998	01	PHO-001	Genomic DNA Isolation and DNALIMS		DNALIMS
	1002	01	PHO-001	Genomic DNA Isolation and DNALIMS		DNALIMS
	1003	01	PHO-000	Genomic DNA Isolation and DNALIMS		DNALIMS
		01	PHO-001	Evaluation of		DNALIMS
				Evaluation of		DNALIMS
				Evaluation of		DNALIMS

- [illegible]

FIG. 11